

Traditional 510(k) (new device)
 Silicon Valley Medical Instruments, Inc.
 510(k) Summary
 CONFIDENTIAL



510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name:	Silicon Valley Medical Instruments, Inc.
Address	47697 Westinghouse Drive, Suite 101, Fremont, CA 94539-7401 USA
Phone Number:	510-897-4695
Fax Number	510-226-1230
Establishment Registration Number	N/A – Not yet registered.
Contact Person	Richard E. Anderson; VP, RA/QA (richarda@svmii.com)
Date Prepared	7 October 2011

Name of Device	
Trade or Proprietary Name	Kodama Intravascular Ultrasound Catheter
Common or Usual Name	Catheter, Ultrasound, Intravascular
Classification Name	Class II
Classification Panel	Cardiovascular
Regulation	21 CFR 870.1200
Product Code(s)	OBJ
Legally Marketed Device(s) to which Equivalence is Claimed	Boston Scientific Corporation's Atlantis SR Pro/Pro 2
Reason for Submission	New device
Device Description	The Kodama Intravascular Ultrasound Catheter is a minimally invasive intravascular ultrasound coronary imaging catheter. The Catheter is a medical device for use by or on the order of a physician. The Catheter emits sound energy from a transducer at the distal tip of the catheter, which is guided into the coronary arteries of the heart. Sound waves that reflect from the inner vascular tissues are received by the transducer and sent to the Console (SVMI's HD-IVUS Ultrasound Imaging System) where a high resolution, cross-sectional image is displayed in real time. The technique provides for in-vivo visualization of the coronary artery lumen, coronary artery wall morphology, and devices (such as stents) at or near the surface of the coronary artery wall.

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The Catheter can be operated at two different frequencies (40MHz or 60MHz) depending on user preference. A telescope allows the imaging of multiple regions of interest in a single procedure by advancing or retracting the imaging assembly without moving the catheter sheath. The Catheter is comprised of the following key components:

- Imaging Assembly

The imaging assembly consists of an ultrasonic transducer, drive cable, transmission line (coaxial cable) and electromechanical rotating catheter to system interface (rotor):

- Transducer
- Drive Cable
- Coaxial Cable
- Rotor

The transducer is attached to the distal end of the drive cable via the distal housing. The drive cable contains the coaxial cable which is electrically terminated at the distal end to the transducer and at the proximal end to an electromechanical rotating interface (rotor). The rotor contains an electrical contact board (rotor board) and provides an electrical interface between the system console and the transducer. In addition, the rotor provides a rotating mechanical interface between the console and drive cable to rotate the drive cable and the transducer. The transducer emits ultrasonic pressure waves (acoustic signals) orthogonally from its face which are reflected back from the region of interest to the transducer surface. The console continuously rotates the drive cable in order to rotationally sweep the transducer beam to image a region of interest.

- Sheath Assembly

The sheath assembly is the outer sleeve of the catheter that houses the imaging core and enters the coronary anatomy. The Sheath Assembly consists of:

- Distal Sheath
- Proximal sheath
- Femoral Marker

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- Lubricious Coating

Distal Sheath

The Distal Sheath consists of:

- Distal Tip
- Imaging Window

Distal Tip

The Distal Tip consists of:

- Soft Tip
- Guide Wire Lumen Entry Port
- Guide Wire Lumen Exit Port
- Guide Wire Lumen
- Radio Opaque Marker
- Flushing Vent

The soft tip comprises the distal most end of the catheter and is the softest member of the sheath assembly. The smaller profile of the soft tip compared to that of the rest of the sheath and its softness ensures good catheter crossability and prevents damage to the vasculature. The Soft Tip includes a guide wire lumen (accessed by a guide wire entry port at the distal end of the soft tip by the proximal end of the guide wire) to engage a guide wire for advancing and retracting the catheter. A radio opaque marker that is visible under fluoroscopy is integrated circumferentially around the guide wire lumen to provide a visual indication of the location of the distal tip. A flushing vent just proximal to the guide wire lumen exit port (located proximal to the distal tip) allows the flushing media to vent out of the sheath.

Imaging Window

Just proximal to the distal tip is the imaging window, the section of the sheath that is transparent to acoustic signals and through which the ultrasound beam is

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emitted and reflected back from the anatomy and regions of interest to be imaged. The flexibility of the imaging window is graded such that it is more flexible at the distal tip and gradually becomes stiffer proximally. The imaging window is bonded to the proximal sheath at the midshaft (proximal most section of the imaging window). The midshaft is of an intermediate stiffness between that of the flexible imaging window and the stiff proximal sheath. The flexibility of the imaging window ensures good catheter trackability.

Proximal Sheath

The proximal sheath is the structural member of the catheter between the distal sheath and the telescope. The proximal sheath material is selected based on mechanical properties that provide sufficient longitudinal stiffness. Proximal sheath stiffness ensures good catheter pushability, allowing the user to access and cross regions of interest. The proximal sheath is distally bonded to the imaging window at the midshaft and proximally bonded to the telescope. The proximal sheath also contains an inner lumen that contains the imaging assembly. The inner lumen is sized to provide sufficient clearance between the drive cable and the inner wall of the lumen, allowing flushing fluid to be delivered to the transducer at the distal end of the imaging assembly to flush air bubbles from the inner lumen and transducer surface that might otherwise compromise image quality.

Femoral Marker

The Femoral Marker is a visual indicator located at a fixed distance from the distal tip on the proximal end of the proximal sheath to alert the user that a pre-determined length of the catheter has been inserted into the patient anatomy. The femoral marker is intended to alert the user that the catheter is about to exit the guide catheter.

Lubricious Coating

The Sheath Assembly is coated with a lubricious coating on the surface of the working length of the catheter sheath to enhance

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	<p>the catheter's ability to advance and retract smoothly into and out from the guide catheter and anatomy and improve catheter movement and crossability.</p> <ul style="list-style-type: none"> • Telescope Assembly <p>The catheter is integrated with a telescope for linear translation of the imaging assembly within the sheath. The telescope remains outside the guide catheter and allows the user to image different regions of the coronary anatomy, during a single procedure, by advancing and retracting the imaging assembly within the anatomy, without having to move the catheter sheath or relocate the distal tip of the catheter. The telescope is mated to the sheath assembly at the proximal end of the proximal sheath via a telescope strain relief.</p> <ul style="list-style-type: none"> • Catheter Hub Assembly <p>The proximal assembly is the proximal most portion of the catheter and is comprised of a Catheter Hub Assembly. The Catheter Hub Assembly consists of the following components and features:</p> <ul style="list-style-type: none"> • Catheter Hub • Electrical Multi Pin Contact Board (rotor board) • Non-Volatile Memory (EPROM) chip • Flushing Port • Fluid Seal • Hub Strain Relief <p>The Catheter Hub Assembly houses the proximal end of the Imaging Assembly, i.e. the catheter to system rotating interface (rotor) which comprises the electromechanical catheter to system interface. Additionally, a multi-pin electrical contact board, integrated into the hub, houses a non-volatile memory device (EPROM chip) that can store performance parameters and console information to improve ease of use. A flushing port located on the top of the hub allows the introduction of flushing fluid to void the sheath assembly and transducer surface of air bubbles that can otherwise interfere with imaging. The hub is also designed with a fluid seal to prevent the ingress of flushing fluid from the catheter to the system console. The catheter hub is mated to the proximal end of the Telescope.</p>
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Intended Use of the Device	The Kodama Intravascular Ultrasound Catheter is intended for ultrasound examination of coronary intravascular pathology only.
Indications for Use	The Kodama Intravascular Ultrasound Catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Summary of the Technological Characteristics of the Device Compared to the Predicate Device		
Characteristic	Predicate	New Device
Materials, Design	Intravascular catheter with PZT transducer at the distal tip and a rotational drive line to enable ultrasound imaging.	Minor changes in materials/design.
Technology	PZT-based intravascular ultrasound.	Same.
Intended Use	The Kodama Ultrasound Imaging Catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.	The Atlantis SR Pro/Pro2 intravascular ultrasound catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Performance Data		
Summary of Non-clinical tests Conducted for Determination of Substantial Equivalence		
Performance Test Summary – New Device		
Characteristic	Standard/Test/FDA Guidance	Results Summary
Performance Testing	Tensile Strength, torque strength, tip flexibility, crossability, pushability, traceability, etc.	Met all specifications.
Biocompatibility Testing	ISO 10993 inc. Cytotoxicity, Hemolysis, and Pyrogenicity.	Compliant with ISO 10993-1.
Sterilization and Shelf Life	EtO Sterilization validation inc. EtO residuals. Shelf life validated to 6 months (for launch).	Compliant with ISO 11135-1.

Comparative Performance Information Summary

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Characteristic	Requirement	New Device	Predicate Device(s)
Sterility	ISO 11135 (Sterile)	Compliant (Sterile)	Compliant (Sterile)
Biocompatibility	ISO 10993	Compliant	Compliant
Ultrasound	ISO 60601-2-37	Compliant	Compliant

Conclusions Drawn from Design Verification/Validation and Non-clinical Data
The Kodama Intravascular Ultrasound Catheter is substantially equivalent in design, materials, and technology to the predicate device(s) with regard to intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

JUN 14 2012

Silicon Valley Medical Instruments, Inc. (SVMI)
c/o Richard E. Anderson
47697 Westinghouse Drive, Suite 101
Fremont, CA 94539-7401

Re: K113008

Trade Name: Kodama Intravascular Ultrasound Catheter

Regulation Number: 21 CFR 870.1200

Regulation Name: Diagnostic intravascular catheter

Regulatory Class: Class II (two)

Product Codes: OBJ

Dated: June 8, 2012

Received: June 11, 2012

Dear Mr. Richard Anderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

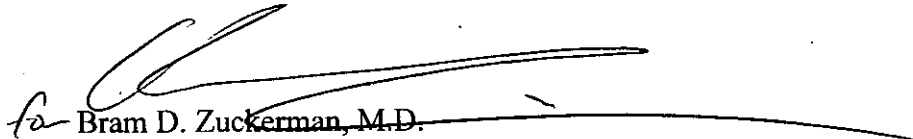
Page 2 - Mr. Richard Anderson

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

510(k) Number:

Device Name: Kodama Intravascular Ultrasound Catheter

Indications for Use: Silicon Valley Medical Instrument's Kodama Intravascular Ultrasound Catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.


Prescription Use ☒ AND/OR Over-The-Counter Use ☐

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
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